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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/637,614	08/11/2000	Shohei Koide	109.034US3	8004

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EXAMINER

PONNALURI, PADMASHRI

ART UNIT


PAPER NUMBER

1639

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/637,614	Applicant(s) Koide	
Examiner Padmashri Ponnaluri	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 10, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-29, 36, and 37 is/are pending in the application.
- 4a) Of the above, claim(s) 15-26, 36, and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Aug 11, 2000 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2, 9 6) ☐ Other:

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DETAILED ACTION

1. This application is a divisional of application 09/096,749 filed on 6/12/98, which claims benefit to a provisional application 60/049,410 filed on 6/12/97.
2. Amendment A, filed on 8/1/00 cancels claims 1-14, 30-35 and 38-39.
3. The amendment A to the specifying pages 43, 45, 52 and 54 has not been entered.
4. Amendment B, filed on 7/26/01 has been fully considered and entered into the application
5. Claims 15-29 and 36-37 are currently pending in this application.
6. Applicant's election without traverse of group I, claims 27-29 in Paper No. 13, filed on 1/10/03 is acknowledged.
7. Claims 15-26 and 36-37 are withdrawn from further consideration pursuant to 37 CAR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 13.
8. Claims 27-29 are currently being examined in this application.
9. Applicants have requested for correction of filing date of the current application on 3/8/02. However, as applicants requested the foreign application data is not found in either priority application 09/096,749 or in the declaration currently filed in this application. This application is a continuation of US Patent application 09/096,749 which claims benefit of provisional application 60/049,410 file don 6/12/97. If applicants think there is a foreign application to which this application gets priority, applicants are requested to file a declaration including the application data.

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10. In this application it is noted that applicants have filed a substituted specification on 12/19/01. The substitute specification filed on 12/19/01 has not been entered because it does not conform to 37 C.F.R. 1.125(b) because: 'the statement as to lack of new matter under 37 C.F.R. 1.125(b) is missing.

11. The corrected or substitute drawings were received on 8/11/00. These drawings are entered into the application.

12. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

13. Claim 27 is objected to because of the following informalities: Claim 27 is dependent on claim 15 which is not being examined in this application. For compact prosecution the limitations of claim 15 are read into claim 27 in this office action. Applicants are requested to amend claim 27 to include claim 15 limitations.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 is vague and indefinite by reciting 'derived from the variegated nucleic acid library of claim 15.' It is not clear what does applicants mean by 'derived from'. Does applicants mean that the peptide of the library of instant is encoded by the nucleic acid from the library of

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claim 15 or the peptide display library of instant claims is same as the claim 15 variegated nucleic acid library or the peptide of the instant library is derived from the nucleic acid of claim 15.

Applicants are requested to amend the claim.

Claim 27 recites the limitation "the variegated nucleic acid library" . There is insufficient antecedent basis for this limitation in claim 27. Applicants are requested to amend the claim to include all the limitations of claim 15. Since claim 15 is not currently being examined in this application.

Claim 28 recites the limitation "the peptide" . There is insufficient antecedent basis for this limitation in the claim or in claim 27. Claim 27 recites peptide display library, not a peptide.

16. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

17. Claims 27-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. .

The instant claims recite a peptide display library derived from the variegated nucleic acid library encoding Fn3 polypeptide monobodies.

The instant specification discloses a fibronectin type III (Fn3) polypeptide monobody comprising plurality of Fn3 β -strand domain sequences that are linked to a plurality of loop region

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sequences. The specification discloses that preferably, one or more loop regions of the monobody comprise amino acid residues: from 15 to 16 inclusive in an AB loop; from 22030 inclusive in a BC loop; from 39-45 inclusive in a CD loop; from 51 to 55 inclusive in a DE loop; from 60 to 66 inclusive in an A. loop; and from 76-87 inclusive in an FG loop. And the further teaches that the methods of making Fn3 monobodies and methods for identifying amino acid sequence of polypeptide capable of binding to a specific binding pair. The specification description of above methods and compositions with Fn3 which clearly do not provide an adequate representation regarding the open ended claimed peptide display library of the presently claimed invention.

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

This holding would be deemed to be applicable to the instant peptide display library derived from the variegated nucleic acid library encoding Fn3; because the peptide display library is derived from the Fn3 nucleic acid library, and the specification description does not disclose the peptides (or peptide library) **derived** from the Fn3 nucleic acid library. The specification does not

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have examples of peptides which are derived (which is interpreted as modified or altered peptides) from the Fn3 nucleic acid library. The specification does not sufficiently teach amino acid sequence or structures of peptide which are derived from nucleic acid library encoding Fn3. And the specifying neither teach how the peptides are derived nor give sufficient identifying characteristics of the derived peptides, to demonstrate possession of the claimed generic(s).

Further according to the claims (claim 15 on which the current claim 27 is dependent) there would be myriad of variegated nucleic acids encoding Fn3 monobodies, because the monobodies comprise any sequence with loop region sequences vary by deletion, insertion or replacement of at least two amino acids. The specification does not teach the residues which are replaced or deleted or added to the loop regions to produce such monobodies.

In the present instance, the claimed invention contains no identifying characteristics regarding the derived peptide libraries and the myriad of monobodies of claim 15.

Additionally, the narrow scope of examples directed to specific monobodies (which are altered) are clearly not representative of the scope of peptide display library of the presently claimed invention.

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

19. Claims 27-29 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,348,584 B1 (Hodgson et al).

The instant claims briefly recite a peptide display library derived from the variegated nucleic acid library encoding Fn3.

Hodgson et al teach fibronectin binding protein compounds and DNA encoding Fibronectin binding proteins and methods for producing such polypeptides recombinantly. The reference teaches that the polypeptides of the invention can be used as immunogens to produce antibodies which include monoclonal or single chain antibodies (i.e., see column 15) (refers to the peptides derived from the library of nucleic acid encoding Fn3 monobody (antibody portion) of the instant claims). The reference teaches phage display technology may be utilized to select antibody genes from naive libraries (i.e., see column 16). Thus the reference teaches peptide display library derived from library encoding Fn3 monobody. The reference teaches variety of expression systems that can be used in the inventions includes bacteriophage (i.e., see column 13). Thus the reference teaches the claimed invention.

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20. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner is on *Increased Flex Schedule* and can normally be reached on Monday to Friday from 7.00 AM to 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri
Primary Examiner
Technology Center 1600
Art Unit 1639
19 March 2003


PADMASHRI PONNALURI
PRIMARY EXAMINER